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EXAMINER	
CLOW, LORI A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/687,483	KOSTER ET AL.	
	Examin r	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- Th MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-17,31-34,43-50,53,54 and 98-108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-17,31-34,43-50,53,54 and 98-108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicants' arguments, filed 12 November 2002, have been fully considered but they are not deemed to be fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The petition to remove restriction requirement filed 10 July 2003 has been granted. Claims 4-17, 31-34, 43-50, 53, 54, and 98-108 are currently pending.

Information Disclosure Statement

The information disclosure statements filed 14 October 2003 has been considered. An initialed copy of PTO form 1449 is included in this Office Action. The information disclosure statement filed 26 March 2003 has been partially considered and is also included in this Office Action. The GenBank Accession numbers, references F-N, have not been considered, as they lack a publication date. The Information Disclosure Statement filed 20 February 2001 has been partially considered. References EB, EC, ED, EE, EF, and EG have not been considered, as they lack a publication date.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6-17, 31, 45-50, 53, and 54 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The database for identifying healthy members of a population which incorporates identifying, obtaining, entering, and storing data, is only a compilation or arrangement of that data. In such a case where data are merely stored as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing process performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer. Such descriptive material is not a process, machine, manufacture, or composition of matter (MPEP 2106, IV, 1(b)).

When nonfunctional descriptive material is recorded on some computer-readable medium, it is not statutory since no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive material stored in a computer-readable medium does not make it statutory. Such a result would exalt form over substance. In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability). Common situations involving nonfunctional descriptive material are:

- a computer-readable storage medium that differs from the prior art solely with respect to nonfunctional descriptive material, such as music or a literary work, encoded on the medium,
- a computer that differs from the prior art solely with respect to nonfunctional descriptive material that cannot alter how the machine functions (i.e., the descriptive material does not reconfigure the computer), or

- a process that differs from the prior art only with respect to nonfunctional descriptive material that cannot alter how the process steps are to be performed to achieve the utility of the invention.

Thus, if the prior art suggests storing a song on a disk, merely choosing a particular song to store on the disk would be presumed to be well within the level of ordinary skill in the art at the time the invention was made. The difference between the prior art and the claimed invention is simply a rearrangement of nonfunctional descriptive material.

In re Sarkar, 588 F.2d 1330, 1333, 200 USPQ 132, 137 (CCPA 1978) ("[E]ach invention must be evaluated as claimed; yet semantogenic considerations preclude a determination based solely on words appearing in the claims. In the final analysis under 101, the claimed invention, as a whole, must be evaluated for what it is.") (quoted with approval in Abele, 684 F.2d at 907, 214 USPQ at 687). See also In re Johnson, 589 F.2d 1070, 1077, 200 USPQ 199, 206 (CCPA 1978) ("form of the claim is often an exercise in drafting"). Thus, nonstatutory music is not a computer component and it does not become statutory by merely recording it on a compact disk. Protection for this type of work is provided under the copyright law.

The arguments pertaining to claims 4 and 5 are persuasive and the rejection under 101 has been withdrawn for those claims.

With respect to claims 6-17, applicant argues that the claims are product claims and that the claimed databases constitute tangible products. This is not persuasive for the reasons outlined above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-17, 31, 43-50, 53 remain rejected under 35 U.S.C. 102(b) as being anticipated by Campbell et al. (WO 98/35609).

Specifically, Campbell et al. teach a computer-based system for predicting the future health of an individual based upon acquiring and analyzing a number of biological and physiological biomarkers. The invention is directed toward providing a computer-based method and apparatus that provides an on-going system for assessing future health risks for a specific individual, and for monitoring the preventative measures taken so as to reduce the future health risks for that individual (page 6, lines 26-29).

In regard to claims 4 and 43, the system comprises a method of obtaining data from healthy members of the population. In particular, the term "specified biological condition" of the invention includes all ranges of health, from the most robustly healthy to the most severely diseased (page 22, lines 13-16). A plurality of biomarker values are obtained from each member of a larger test population (page 13, lines 3-4). The values are placed in a computer (see computer-system description on page 13) and the observations are associated with each member. These can be scalar or vector and imply an indexer (page 13, lines13-17). The database is stored on a computer-readable medium (page 13, lines 19-23; page 14, lines 3-4).

In regard to claims 5 and 44, the results are entered into the database and the samples can come from a variety of sources, such as saliva (body fluid), or toenails (biological sample), for example (page 16, lines 13-18).

In regard to claims 6-8 and 45-46 the invention inherently comprises a database with the above information.

In regard to claim 9, the database can comprise information on a variety of bio-markers, including nutritional and life-style bio-markers (page 16, lines 25-26). The total number of bio-markers that may be used is unlimited in principal (page 19, lines 11-13). For example, if the biological condition is acquiring coronary heart disease within a specified time, serum cholesterol, glucose intolerance, systolic blood pressure, or cigarette smoking may be used as bio-markers (page 31, lines 23-28).

In regard to claims 10 and 47, the organisms of Campbell et al. are mammals (human patients; speaks of risks to persons, page 5).

In regard to claim 11, samples are collected from blood, blood fractions, cells, and organelles (see Table 1, beginning page 17).

In regard to claims 12-15 and 48-50, the data could be phenotypic data, physical data, or genotypic data (see page 9, biomarkers can be physiologic and biochemical).

In regard to claim 16, the database and system of Campbell et al. is a relational database because it includes information from populations and sub-populations for comparisons (page 26, lines 10-31).

In regard to claims 17 and 53, values are placed in a computer (see computer-system description on page 13) and the observations are associated with each member. These can be scalar or vector and imply an indexer (page 13, lines13-17).

In regards to claim 31, the database is contained in a computer system (page 13, lines 19-23).

Arguments: 35 USC 102(b) Rejections: Anticipation by Campbell et al.

Applicant provides an overview of the claims of the instant application on pages 20-24. At page 24, beginning line 5, Applicant asserts that Campbell et al. do not disclose excluding the most severely diseased from its database, nor does the reference provide any motivation for doing so. This is not persuasive. Nowhere in the claim language is there a limitation including "exclusion of the most severely diseased" language. Furthermore, the instant invention is intended to provide information pertaining to the genomic basis for disease and to elucidate gene markers thereof (specification, page 4). The invention takes samples from the population based upon a "healthy" categorization of the individual. Campbell et al. also take samples from large populations in effort to provide a tool for assessing an individual subject's risk of future disease (page 6). Campbell et al. do not state that only disease verses healthy individuals are analyzed in this system and method. Rather that it is a system to establish an assessment of future health risks. This method is applicable to a large population of any individual. There is no guarantee in the instant invention that only healthy individuals will exist in the population, for this is a relative evaluation based upon only certain criterion.

Applicant further argues at page 25, line 8, that Campbell et al. do not disclose a database obtained from members of a population selected on the basis of their being healthy. However, healthy members are included in Campbell et al., as discussed above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32-34, 99, 100, and 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0596205 A2 (Bullaughey et al.; Published 5 November 1994, PTO Form 1449, 20 February 2001, Reference BU), in view of Campbell et al. (WO 98/35609), in further view of US 5,498,545 (Vestal; published 12 March 1996; PTO Form 1449, 20 February 2001, Reference AI).

EP 0596205 A2 teaches an analytical system which is responsible for coordinating the operations of various hardware instruments in carrying out a bench method or bench sequence (see abstract). The bench hardware comprises a variety of instruments as well as a transport instrument.

In regard to claims 32 and 33, EP 0596205 A2 teaches a Bench Supervisor system such that a user can prepare a sample, and analyze the sample in the appropriate instrument. After the first method is complete, the system can pass the sample on to a next location for analysis (processing station equivalent). The next instrument, for example, could include a liquid chromatograph or a mass spectrometer chemstation (claim 33) (page 16, lines 1-16). The bench method assembles methods from the different instrument applications to process a sample from start to finish, in an uninterrupted process (page 16, lines 26-29). The bench system tracks the inputs and outputs from each instrument and passes the information along to the next instrument method (page 16, lines 26-28).

In regard to the limitation that the database of claim 8 is included in the process system, EP 0596205 A2 provides the motivation to include the database of Campbell et al. (as recited above) in the analysis system by stating that the instruments include means for processing samples, transporting samples, and one or more resources to process the sample. The system

may also advantageously include means for employing other programs to produce output data and a means for making decisions relative to the process sample, enabling the system to modify a method or re-direct a sample or change analysis of a function of an intermediate result (page 2, lines 50-55). It would have been prima facie obvious to one of skill in the art at the time of the invention to include the database of claim 8 in the automated process system of EP 0596205 A2.

In regard to claim 34, EP 0596205 A2 does not specifically teach that the mass spectrometer chemstation includes analysis systems, however, it was well known to one of skill in the art at the time of the invention that a mass spectrometer system would include an analysis such that sample signals are analyzed and a quantitative result is obtained. This is evidenced by US 5,498,545 which teaches a system for analyzing multiple samples by mass spectrometry. The MALDI mass spectra system of the invention includes a step to convert time-of-flight spectrum into mass spectrum. Peaks are extracted and intensity of peaks analyzed. The computer interprets the results to yield, in this case, a sequence of bases in a DNA fragment (column 12, lines 47-58 and column 13, lines 7-11). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to include such a system of MALDI spectrometry in the bench system of EP 0596205 A2, where the motivation is provided by US 5,498,545.

Claims 54 and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0596205 A2 (Bullaughey et al.; Published 5 November 1994), in view of Campbell et al. (WO 98/35609).

EP 0596205 A2 teaches a Bench Supervisor system such that a user can prepare a sample, and analyze the sample in the appropriate instrument. After the first method is complete,

the system can pass the sample on to a next location for analysis (processing station equivalent). The next instrument, for example, could include a liquid chromatograph or a mass spectrometer chemstation (claim 33) (page 16, lines 1-16). The bench method assembles methods from the different instrument applications to process a sample from start to finish, in an uninterrupted process (page 16, lines 26-29). The bench system tracks the inputs and outputs from each instrument and passes the information along to the next instrument method (page 16, lines 26-28).

While EP 0596205 A2 does not teach the database of claim 8, Campbell et al. do, as recited above. EP 0596205 A2 provides the motivation to include the database of Campbell et al. (as recited above) in the analysis system by stating that the instruments include means for processing samples, transporting samples, and one or more resources to process the sample. The system may also advantageously include means for employing other programs to produce output data and a means for making decisions relative to the process sample, enabling the system to modify a method or re-direct a sample or change analysis of a function of an intermediate result (page 2, lines 50-55). It would have been prima facie obvious to one of skill in the art at the time of the invention to include the database of claim 8 in the automated process system of EP 0596205 A2.

Claim 98 is rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al. (WO 98/35609), in further view of US 5,498,545 (Vestal; published 12 March 1996).

As stated above Campbell et al. teach a computer-based system for predicting the future health of an individual based upon acquiring and analyzing a number of biological and physiological biomarkers. The invention is directed toward providing a computer-based method

and apparatus that provides an on-going system for assessing future health risks for a specific individual, and for monitoring the preventative measures taken so as to reduce the future health risks for that individual (page 6, lines 26-29).

Campbell et al. does not specifically teach that the bio-marker data come from a mass spectrometric analysis. However, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to use mass spectrometer analysis of Vestal, who teaches a system for analyzing multiple samples by mass spectrometry (see abstract) on the samples included in the database of Campbell et al. The motivation to do so is provided by Campbell et al. at page 20, line 20-23, which states that the use of biomarker data obtained from any source falls within the spirit and scope of the invention.

Claims 103-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0596205 A2 (Bullaughey et al.; Published 5 November 1994), in view of Campbell et al. (WO 98/35609), in view of US 5,498,545 (Vestal; published 12 March 1996), in further view of US 6,602,662 B1 (Koster et al.; Published 5 August 2003; priority 18 March 1996; PTO 1449, 14 October 2003, Reference H).

EP 0596205 A2 teaches an analytical system which is responsible for coordinating the operations of various hardware instruments in carrying out a bench method or bench sequence (see abstract). The bench hardware comprises a variety of instruments as well as a transport instrument.

In regard to claims 103-108, EP 0596205 A2 teaches a Bench Supervisor system such that a user can prepare a sample, and analyze the sample in the appropriate instrument. After the first method is complete, the system can pass the sample on to a next location for analysis

(processing station equivalent). The next instrument, for example, could include a liquid chromatograph or a mass spectrometer chemstation (claim 33) (page 16, lines 1-16). The bench method assembles methods from the different instrument applications to process a sample from start to finish, in an uninterrupted process (page 16, lines 26-29). The bench system tracks the inputs and outputs from each instrument and passes the information along to the next instrument method (page 16, lines 26-28).

In regard to the limitation that the database of claim 8 is included in the process system, EP 0596205 A2 provides the motivation to include the database of Campbell et al. (as recited above) in the analysis system by stating that the instruments include means for processing samples, transporting samples, and one or more resources to process the sample. The system may also advantageously include means for employing other programs to produce output data and a means for making decisions relative to the process sample, enabling the system to modify a method or re-direct a sample or change analysis of a function of an intermediate result (page 2, lines 50-55). It would have been prima facie obvious to one of skill in the art at the time of the invention to include the database of claim 8 in the automated process system of EP 0596205 A2.

EP 0596205 A2 does not specifically teach that the mass spectrometer chemstation includes analysis systems, however, it was well known to one of skill in the art at the time of the invention that a mass spectrometer system would include an analysis such that sample signals are analyzed and a quantitative result is obtained. This is evidenced by US 5,498,545 which teaches a system for analyzing multiple samples by mass spectrometry. The MALDI mass spectra system of the invention includes a step to convert time-of-flight spectrum into mass spectrum. Peaks are extracted and intensity of peaks analyzed. The computer interprets the results to yield,

in this case, a sequence of bases in a DNA fragment (column 12, lines 47-58 and column 13, lines 7-11). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to include such a system of MALDI spectrometry in the bench system of EP 0596205 A2.

Finally, EP 0596206 A2 does not specifically state that the samples are analyzed by primer oligo base extension (PROBE), as required by claims 103-108. However, US 6,602,662 B1 does teach a mass-spectrometry based process for detecting nucleic acid molecules and sequences in the molecules which comprises hybridizing a nucleic acid molecule with a primer oligonucleotide that is complementary to a sequence that is adjacent to a region suspected of containing the target nucleotide; contacting the hybridized primer with dideoxynucleoside triphosphate and a polymerase to that it is extended onto the primer and; detecting the primer (see, for example, column 29; see claim 1). Column 13-14 further describes the methods whereby ligation and cleavage are used in nucleic acid detection. It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to use the PROBE method in mass spectrometry analysis in the system of EP 0596205 A2 which includes the database of Campbell et al. The motivation being that the PROBE mass spectrometry method is particularly useful for diagnosing a predisposition to a disease or condition (column 3, lines 54-63).

35 USC 103(a) Rejections: Unpatentable over Campbell et al. in view of Koster

Applicant's arguments are moot in view of the new grounds of rejection.

No Claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (571) 272-0549.

Marjorie A. Moran

MARJORIE MORAN
PATENT EXAMINER

January 23, 2004
Lori A. Clow, Ph.D.
Art Unit 1631
Lori A. Clow